

**Remarks**

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. The instant method and apparatus claims refer to devices comprising one or more capillary channels, in which the relative hydrophobicity of regions within at least one capillary channel differs. In certain embodiments, this differing hydrophobicity is used to control the rate and/or direction of fluid flow through the devices.

Claims 1-5 and 7-18 are presently pending, with claims 6 and 19-21 having been cancelled previously. Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing remarks.

*Interview Summary*

Applicant's representative briefly discussed the status of the case with the Examiner by telephone on about 2/20/04. During the telephone call, Applicant's representative briefly discussed the general substance of the arguments described herein. The Examiner took no position and suggested for Applicant to file the arguments in full as an after final response. Applicant wishes to thank the Examiner for agreeing to consider the following remarks.

*Art-Based Remarks*

**Obviousness-type double patenting**

Applicant acknowledges the clarified rejection of claims 1-18 as allegedly being unpatentable over U.S. Patents 6,156,270; 6,019,944; 5,885,527; and 5,458,852. A terminal disclaimer is submitted herewith, rendering the rejection as moot.

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1-18 under 35 U.S.C. §102(e), as allegedly being anticipated by Kuhn *et al.*, U.S. Patent 5,202,268 (“the ‘268 patent”).

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only when a *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. *See, e.g.*, *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

In the previous office action (Paper no. 9), the Examiner based the rejection on the alleged disclosure of a liquid flow path in the ‘268 patent through two porous layers, and to claim 4, which states that one of the layers may be hydrophilic and the other hydrophobic. In reply, Applicant described in detail why the rejection was in error, and provided evidence in the form of a declaration establishing that a porous material is not equivalent to the capillary channel of the present claims. Indeed, Applicant noted that the instant specification clearly distinguishes between porous materials and capillary channels.

In the current Office Action (Paper 010704), the Examiner agreed with Applicant’s arguments that flow through a capillary channel differs from flow through a porous material. *See, e.g.*, Office Action, page 4 (“The Office agrees with all of the characterization made about what is intended by a channel”). Nevertheless, the Examiner has maintained the rejection, asserting for the first time that certain “impermeable barriers” discussed in column 4, lines 40-46 of the ‘268 patent “fairly read on the claimed channels.” *Id.* Applicant disagrees with this characterization of the teachings of the ‘268 patent.

*a) There is no disclosure of a capillary channel in the '268 patent*

There is no disclosure of a capillary channel in the '268 patent and the "impermeable barriers" referred to by the Examiner do not form any capillary channel. For example, fluid flow in the devices disclosed in the '268 patent is not mediated by capillary force generated between surfaces of the "impermeable barriers." Instead, as described in the '268 patent, the barriers merely serve to impede lateral flow of fluid from a sample receiving site in the porous material, so that fluid applied to the porous material may wick into the porous material in a desired fashion. '268 patent, column 4, lines 31-43.

It is respectfully submitted that the burden of establishing the existence of a capillary channel by inherency in the formed by the "impermeable barriers" of the '268 patent requires the Examiner to provide extrinsic evidence that the channel necessarily is present in this entity. MPEP §2112. The fact that a certain result or characteristic may occur is not sufficient to establish the inherency of that characteristic. *See, e.g., In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). Applicant respectfully submits that because the Examiner has not met this burden, no *prima facie* case of anticipation has been established in this case.

*b) There is no disclosure of a first capillary region comprising a hydrophilic surface*

There is no disclosure of a first capillary region comprising a hydrophilic surface in the '268 patent and the Examiner has failed to identify any such region. The present claims refer to introducing fluid into a capillary channel, where the capillary channel comprises two regions: a first region comprising a hydrophilic surface, and a second region comprising a hydrophobic surface. According to the claims, the fluid flows through the first capillary region of the capillary channel to contact the hydrophobic surface of the second capillary region of the capillary channel. The hydrophilic surface of the first capillary regions clearly refers to a surface of the capillary.

In contrast, the '268 patent discloses applying fluid to a first porous member, whereby flow of that fluid through a device is mediated by the characteristics of the porous members

present. '268 patent, column 2, lines 55-68. The '268 patent refers to a hydrophilic material as the Examiner pointed out in the first Office Action. However, such hydrophilic material is a reference to a wicking layer, an element that the Examiner now admits is not the capillary. Thus, there is no teaching in the '268 patent for a capillary, let alone a first capillary region with a hydrophilic surface.

*c) There is no disclosure of a second capillary region comprising a hydrophobic surface adjacent to said first capillary region*

There also is no disclosure of a second capillary region comprising a hydrophobic surface in the '268 patent and the Examiner has failed to identify any such region. The hydrophilic surface of the second capillary regions clearly refers to a surface of the capillary.

In contrast, the '268 patent discloses applying fluid to a first porous member, whereby flow of that fluid through a device is mediated by the characteristics of the porous members present. '268 patent, column 2, lines 55-68. The '268 patent refers to a hydrophobic material as the Examiner pointed out in the first Office Action. However, such hydrophobic material is a reference to a wicking layer, an element that the Examiner now admits is not the capillary. Thus, there is no teaching in the '268 patent for a capillary, let alone a second capillary region with a hydrophobic surface.

*d) There is no disclosure of fluid flowing through said first capillary region to contact the hydrophobic surface of the second capillary region.*

As there is no disclosure of a capillary channel in the '268 patent and no disclosure of first (hydrophilic) and second (hydrophobic) capillary surfaces, there clearly cannot be any disclosure of fluid flowing through said first capillary region to contact the hydrophobic surface of the second capillary region. This constitutes yet another undisclosed element of the claims lacking in the '268 patent.

*e) Response to comments raised by the Examiner*

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Applicant respectfully disagrees with the Examiner's statement that "Kuhn et al. teaches an identical structure to that claimed and performs the identical method of applying a sample in a channel to migrate to a reagent" (Office Action, page 4). Rather than being an "identical structure" performing an "identical method," the '268 patent uses an entirely different structure to perform an entirely different method. Moreover, even if one assumes solely for the sake of argument that the "impermeable barriers" of the '268 patent might form a capillary channel, nothing in the '268 patent indicates that such a channel would comprise the two surface regions referred to in the present claims. Indeed, not even the Examiner considers this to be the case, apparently relying instead on the porous members to provide the hydrophilic and hydrophobic surfaces referred to in the present claims. Again, Applicant respectfully submits that flow through a capillary channel differs from flow through a porous material, and that the porous materials referred to in the '268 patent are not equivalent to two regions within a capillary channel as described in the present claims.

Applicant also notes a continuing defect in the rejection: nothing of record indicates how the cited publication reads on claims 2 and 6, and their dependent claims. These claims describe the use of the hydrophobic surface to control the rate or direction of flow into a third capillary region of the device. Likewise, the Examiner has not indicated how the cited publication reads on claims 3 and 12, which indicate that a hydrophobic region is used to delay fluid flow until the region is rendered hydrophilic. Applicant respectfully requests that the Examiner indicate where such elements may be found in the cited patent, so that Applicant may have a reasonable opportunity to respond.

Because the cited '268 patent fails to teach each and every element of the present claims, Applicant respectfully submits that no *prima facie* case of anticipation has been established. Applicant therefore requests that the rejection under 35 U.S.C. §102 be reconsidered and withdrawn.

## CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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